

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)
_____)

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:)

Suits Naming the Tennessee Clinic)
Defendants)
_____)

**TENNESSEE CLINIC DEFENDANTS' OPPOSITION TO THE
MASSACHUSETTS BOARD OF PHARMACY'S MOTION FOR PROTECTIVE ORDER**

Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants" or the "Defendants") oppose the Massachusetts Board of Registration in Pharmacy's (hereinafter, at times, "the Board") Motion for Protective Order.¹

The Board asks the Court to create an exception to Fed. R. Civ. P. 30(b)(6), and exempt it from producing a witness for deposition, claiming a deposition "might" impact the *federal* criminal prosecution of NECC's owners.² Unsupported by any legal precedent, the motion likewise offers nothing other than factual conclusions as to why the Board's deposition *could* impact actions by an unrelated governmental agency. The motion ignores the severe prejudice to the Tennessee Clinic Defendants if they cannot depose the Board. Accordingly, the motion should be denied.

¹ The Board's Motion is at Dkt. 1975, and the Memorandum of Law is at Dkt. 1976.

² Often referred to in this litigation as the NECC "insiders."

1. Introduction

Despite the PSC's repeated demand to set their claims against the Tennessee Clinic Defendants for trial in this calendar year,³ numerous parties and non-parties deploy every roadblock available in an effort to prevent the Tennessee Clinic Defendants from obtaining the discovery necessary to appropriately defend these cases. The Massachusetts Board of Pharmacy joins a long line of individuals and entities refusing to participate in discovery, citing a host of excuses. In what is now a multi-act theatre of the absurd, 14 different parties and non-parties move the Court for protective orders to avoid testifying under oath.⁴

Eighty-eight percent of the 143 cases transferred to the District of Massachusetts from the District of Tennessee were filed by Tennessee residents, against Tennessee healthcare providers, for injuries that occurred in Tennessee.⁵ Tennessee substantive law governs the claims. The modified comparative fault rule has been an established element of Tennessee law since the 1992 decision by the Tennessee Supreme Court in *McIntyre v. Balentine*.⁶ In addition to eliminating the doctrine of joint and several liability in Tennessee,⁷ *McIntyre* made relevant all evidence that "a non-party caused or contributed to the injury or damage for which recovery is sought."⁸ The Tennessee Clinic Defendants are not seeking depositions of tangential non-parties with information

³ Dkt. 1882.

⁴ The absurdity is evident in that the Board does not even move for protection based on a burden on the Board. The state Board moves for protection based on second-hand "concerns" voiced by *an employee of an unrelated federal agency*. With this motion, a non-party witness is claiming it cannot produce a witness for a deposition because *someone else* has said that the non-party's deposition *might* impact something another governmental agency is doing.

⁵ The remaining cases were filed by Kentucky residents who sought and received treatment from Tennessee health care providers at a facility in Tennessee. Tennessee substantive law also governs their claims.

⁶ 833 S.W.2d 52 (Tenn. 1992).

⁷ *Id.* at 58 ("...today's holding renders the doctrine of joint and several liability obsolete.")

⁸ *Id.*

of questionable value. The Tennessee Clinic Defendants seek to depose central players in these cases, including:

- NECC, the entity that contaminated the drugs and caused the entire outbreak.⁹
- Barry Cadden, the lead pharmacist who ran the company that contaminated the drugs and interacted at key times with the Tennessee Clinic Defendants.¹⁰
- Glenn Chin, the pharmacist responsible for compounding the contaminated medications.¹¹
- Medical Sales Management, the company that represented to the Tennessee Clinic Defendants that NECC's medications were safe and sterile.¹²
- The FDA, the governmental regulators who knew that NECC was operating illegally, but did nothing.¹³
- The Massachusetts Board of Pharmacy, the state entity that licensed NECC and inspected it in May 2011 (a month before the Tennessee Clinic Defendants began receiving product from NECC).¹⁴

Without depositions of representatives of these entities, the Tennessee Clinic Defendants are denied access to evidence clearly relevant to proof of comparative fault, unfairly denied evidence which rebuts the Plaintiffs' causation theory, and stripped of the ability to utilize conventional methods to discover the basic facts necessary to respond to the Plaintiffs' claims. These motions for protective order – including, now, the Massachusetts Board's – if granted, unfairly prejudice the Tennessee Clinic Defendants.¹⁵

⁹ It refuses to give a deposition. [Dkt. 1810]

¹⁰ He refuses to give a deposition. [Dkt. 1823]

¹¹ He refuses to give a deposition. [Dkt. 1823]

¹² It refuses to give a deposition. [Dkt. 1854]

¹³ It refuses to give a deposition. [Dkt. 1838]

¹⁴ It refuses to give a deposition. [Dkt. 1975]

¹⁵ This does not even mention the fundamental unfairness motions like this perpetuate. NECC and its insiders knowingly lied to the Tennessee Clinic Defendants about the sterility of its products. The Tennessee Clinic Defendants relied on these misrepresentations to their (and their patients') terrible detriment. Yet, the Tennessee Clinic Defendants cannot prove this at trial because NECC and its insiders

Balanced against the obvious prejudice, the impact of a deposition on the Massachusetts Board of Pharmacy is slight. The Board's motion for protective order falls far short of meeting the high burden required to justify the requested relief. It should be denied.

2. Efforts to obtain information from the Massachusetts Board of Pharmacy

The old adage, "no good deed goes unpunished," applies here. This motion comes after a long effort by the Tennessee Clinic Defendants to obtain relevant information from the Board:

- Nearly three (3) years ago, the Tennessee Clinic Defendants, recognizing that information held by the Board would be important in potential litigation, requested the Board's file on NECC in *October 2012*. The Board responded to the request by providing a three (3) page printout of NECC's licensure page from the Board's website.
- With public scrutiny of the Board increasing, later in October 2012, the Board publicly disclosed approximately 1,000 pages of documents from its NECC file. Yet, the disclosure still fell thousands of documents short of the information in the Board's possession.^{16 17 18}

hide behind the criminal charges and the bankruptcy to avoid providing testimony. Likewise, the FDA and the Massachusetts Board allowed NECC to continue compounding medication, despite their knowledge that NECC was operating illegally. The Massachusetts Board even inspected and licensed NECC *the month prior to* the Tennessee Clinic Defendants' first purchase from NECC. Yet, the Tennessee Clinic Defendants cannot prove this at trial because the FDA and Board refuse to provide deposition testimony. NECC, the FDA, and, now, the Board, all seek as a collateral benefit to their misconduct the ability to avoid oral discovery, to the great prejudice of the Tennessee Clinic Defendants.

¹⁶ <https://www.bostonglobe.com/metro/2012/10/22/mass-compounding-pharmacy-has-long-list-violations-cleared-outside-monitor-now-jail/zusDQSurMqUXwuhavf5KEJ/story.html>.

¹⁷ The Board never explained why it only disclosed three (3) pages when the Tennessee Clinic Defendants requested the file, but disclosed 1,000 pages publicly as public scrutiny turned to the Board.

¹⁸ The Board later informed the Tennessee Clinic Defendants that it actually had at least 15,000 NECC-related documents. (See letter from Board, June 12, 2015, attached as Exhibit 1).

- On March 18, 2015, as common discovery continued in the MDL, the Tennessee Clinic Defendants served a subpoena and Fed. R. Civ. P. 30(b)(6) notice on the Board.¹⁹ The notice identified 18 specific topics, organized by category, and nine (9) specific document requests.²⁰
- The Board requested additional time to make written objections to the subpoena, accompanied by a cut-and-paste litany of form objections.²¹ Nowhere in the written objections was there any mention of the need to stay the deposition due to the federal criminal prosecution. The Tennessee Clinic Defendants promptly responded, addressing each and every objection.²²
- Lengthy meet-and-confers were held in April. During the meet-and-confer process, the Board never expressed any concern that producing a witness could impact the federal criminal prosecution. Because the Tennessee Clinic Defendants understood the process to be working toward document production and a deposition of the Board, the Tennessee Clinic Defendants agreed to postpone the deposition, and aim for a June 15, 2015, deposition date.²³ In fact, the Board was apparently working to identify a designee as of April 29, 2015.²⁴
- The next contact from the Board came in a brief, conclusory letter dated June 4, 2015, in which the Board refused to produce a witness, and demanded a stay on any deposition of the Board.²⁵
- The Tennessee Clinic Defendants refused to adhere to this unilaterally imposed stay and told the Board to file its motion for protective order, which it did on June 16.²⁶

At this point, 45 days after the deposition was supposed to be taken, and almost four months after the subpoena was issued, no documents have been produced and no designation of a witness has occurred.

¹⁹ Dkt. 1735.

²⁰ The Tennessee Clinic Defendants did not simply serve a notice on the Board for a witness to testify on “everything related to the outbreak.” Instead, to minimize the burden on the Board, the Tennessee Clinic Defendants spent significant time to narrowly tailor the topics and document requests.

²¹ See April 8, 2015, letter from Board (attached as Exhibit 2).

²² See April 21, 2015, letter from Tennessee Clinic Defendants (attached as Exhibit 3).

²³ Dkt. 1792.

²⁴ See April 29, 2015, emails (attached as Exhibit 4).

²⁵ See June 4, 2015, letter from Board (attached as Exhibit 5).

²⁶ See June 9, 2015, letter to Board (attached as Exhibit 6).

3. The testimony from the Massachusetts Board of Pharmacy is essential to the Tennessee Clinic Defendants' defense of the claims against them.

No one involved in this litigation disputes that the Board holds information *crucial* to the Tennessee Clinic Defendants' defense of these cases. Without this information, the Tennessee Clinic Defendants cannot mount a full and fair defense. This is not hyperbole. The testimony of the Board – and of the FDA and NECC – is indispensable to the Tennessee Clinic Defendants.

Four (4) simple reasons justify the long-standing effort to depose the Board:

First, the Tennessee Clinic Defendants asserted that the comparative fault of the Board caused or contributed to the Plaintiffs' injuries.²⁷ Demonstrating the comparative fault of the Board authorizes the jury to allocate fault to the Board, reducing any degree of fault assigned to the Defendants.²⁸

This is not an aspirational defense that will never be presented to the jury. The Board publicly admitted (1) that it breached its duty in allowing NECC to operate after receiving multiple complaints,²⁹ and that the breach contributed to cause the outbreak³⁰. The Tennessee Clinic Defendants require deposition testimony to establish the *comparative* degree or percentage of fault of the Board shared with the FDA and others. Without it, this viable defense is impaired.

²⁷ Master Answer to Master Complaint, Dkt. 1455, p. 90-100.

²⁸ See *Carroll v. Whitney*, 29 S.W.3d 14, 19 (Tenn. 2000) (holding jury can allocate fault to immune non-parties).

²⁹ See November 7, 2012, statement by Board: "I also expect the staff charged with oversight to perform their duties to the highest standards. That failed to happen here." available at <http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/121107-statement-from-lauren-smith.doc> (last accessed June 29, 2015).

³⁰ *The Fungal Meningitis Outbreak: Could It Have Been Prevented?: Hr'g Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 112th Cong. 51-52 (Nov. 14, 2012) (statement of Lauren Smith, MD, Interim Commissioner of the Massachusetts Department of Public Health) (acknowledging that the Board's "[p]oor judgment, missed opportunities, and lack of appropriate action" "contributed" to the outbreak) available at <http://www.gpo.gov/fdsys/pkg/CHRG-112hhrg88248/pdf/CHRG-112hhrg88248.pdf> (last accessed June 29, 2015).

Second, important factual information held only by the Board supports the Tennessee Clinic Defendants' rebuttal of the Plaintiffs' claims.

For example, the Plaintiffs contend that the standard of care required the Tennessee Clinic Defendants to call the Board and ask about NECC's history before purchasing product from NECC.³¹ The Plaintiffs pursued this point in depositions.³² The Plaintiffs assert that, had the Tennessee Clinic Defendants asked the Board about NECC before purchasing, the outcome would have changed. This theme makes relevant *when* and *what* information the Board would have disclosed had anyone requested information regarding NECC, along with the obvious inquiry of whether anyone ever sought the information. A deposition of the Board or its employees offers the information to answer this theme from the Plaintiffs.

The Plaintiffs contend that the Tennessee Clinic Defendants should have undertaken a "site visit" of NECC prior to purchasing.³³ That theme includes the obvious element of what a "site visit" would have shown. *The Board* conducted such a "site visit" of NECC in May 2011, *a month* before the Tennessee Clinic Defendants began purchasing product from NECC. *The Board deemed NECC safe to operate.*³⁴ The Tennessee Clinic Defendants need to establish this in a deposition to rebut the Plaintiffs' claim that a site visit would have changed the outcome.

³¹ See Reed Complaint, Case No. 1:13-cv-12565-RWZ, Dkt. 1, ¶ 249(e).

³² See Deposition of Debra Schamberg, p. 83 ("Did you contact the Massachusetts Board of Pharmacy at any time regarding NECC?"); 83-84 ("Did you ask the sales representative whether NECC had ever been disciplined by either the FDA or the Massachusetts Board of Pharmacy?"); 149 ("Did you make any effort to call the Massachusetts Board of Pharmacy and say, 'What is this about?'").

³³ Master Complaint, Dkt. 545, ¶ 192(c).

³⁴ <https://www.bostonglobe.com/lifestyle/health-wellness/2012/10/23/new-england-compounding-did-not-follow-sterility-procedures-state-revokes-pharmacy-license-and-orders-regular-inspections-similar-compounders/VNhs9sUUb8Pl1OfIFOeKEP/story.html> ("An inspection by pharmacy board staff on May 24, 2011, did not uncover any sanitation problems. In fact, the report released Monday by the Department of Public Health said the pharmacy was kept clean and organized, and the inspector concluded: 'Inspection satisfactory.'")

The Tennessee Clinic Defendants also seek to resolve unexplained, material ambiguities in the limited Massachusetts Board of Pharmacy documents already in hand. The FDA's 2002 Compliance Policy Guidance on Pharmacy Compounding³⁵ makes clear the duty of the FDA to strictly police and regulate companies *manufacturing* pharmaceutical products for use in the United States. NECC is described as a *manufacturer* in joint FDA/Massachusetts Board of Pharmacy documents.³⁶ However, despite factual findings that unquestionably support the conclusion that NECC was a manufacturer,³⁷ NECC was categorized as a compounder, not a manufacturer, after a joint FDA/Massachusetts Board of Pharmacy meeting in February of 2003, allegedly memorialized in minutes from the Board that have yet to be produced.³⁸

Third, the Board holds information directly relevant to the fault of other parties. Again, this is not a theoretical defense; the fault of other parties will be presented for the jury to consider at trial.³⁹ The Board's post-outbreak investigation concluded that NECC failed to meet sterility standards, information directly relevant to NECC's fault. The Board has publicly criticized the FDA for its failure to meet its regulatory duty, which is directly relevant to the FDA's fault. The Tennessee Clinic Defendants need to establish

³⁵ CPG 460.200 (May 2002) available at http://www.fda.gov/ohrms/dockets/98fr/02d-0242_gdl0001.pdf (last accessed June 29, 2015).

³⁶ See documents produced by the Board (as part of the ~1,000 pages of documents made publicly available) attached as Exhibit 7 and Bates numbered Mass BOP-00916-18.

³⁷ See summary of 2002 joint inspection of NECC conducted by the Board and the FDA attached as Exhibit 8 and Bates numbered Mass BOP-00921-43. (NECC prepares and dispenses product in bulk – Mass BOP-934); (sterile products are compounded before prescriptions are received – Mass BOP-935); (NECC dispensed medication for 20,000 prescriptions in 2002 and shipped out of state – Mass BOP-936).

³⁸ See FDA memorandum from meeting attached as Exhibit 9 and Bates numbered Mass BOP-00888-92 (attachments to memorandum omitted); see also Exhibit 8 at Mass BOP-940.

³⁹ See *Dotson v. Blake*, 29 S.W.3d 26, 28-29 (Tenn. 2000) (explaining that Tennessee's comparative fault scheme is designed to link liability to fault so as to "achieve the fairest result possible" and noting that, with *Carroll v. Whitney*, Tennessee "joined the majority of jurisdictions that permit the allocation of fault to all tortfeasors, even immune ones, who cause or contribute to the plaintiff's injuries. Specifically, [the court] concluded that 'when a defendant raises the non-party defense in a negligence action, a trier of fact may allocate fault to immune nonparties.'") (additional cites omitted).

these facts in a deposition to support their comparative fault claims against these other parties and non-parties.

Finally, the PSC has specifically put the Board's regulatory authority at issue in these cases. The Plaintiffs contend that NECC had a "well-known history of adverse events" with the Board.⁴⁰ The Plaintiffs suggested through questioning of witnesses that the Tennessee Clinic Defendants should not have relied on the fact that NECC was licensed by the Board because the Board had insufficient resources to regulate NECC.⁴¹ The Tennessee Clinic Defendants must be allowed to obtain testimony from the Board to refute these contentions about the Board's authority.

* * * * *

Like NECC, NECC's insiders, and the FDA, the Massachusetts Board of Pharmacy holds information that is vital to the Tennessee Clinic Defendants' ability to prove that they complied with the standard of acceptable practice, to establish that other parties and non-parties were at fault for the Plaintiffs' injuries, and to directly rebut elements of the Plaintiffs' claims. To eliminate the Tennessee Clinic Defendants' right to take the Board's deposition based on the weak arguments in the motion for protective order severely prejudices the Tennessee Clinic Defendants.⁴²

⁴⁰ *Reed* Complaint, Case No. 1:13-cv-12565-RWZ, Dkt. 1, ¶ 79.

⁴¹ See Deposition of Michael Cotugno, p. 159-60 ("And although a compounding pharmacy may have been regulated by a state board of pharmacy, for instance here NECC by the Mass. Board of Pharmacy, you also were aware back in the 2008 timeframe, in that timeframe, that they had – the Mass. Board of Pharmacy had limited resources to do inspections and audits of compounding pharmacies. Correct?"; "Weren't you aware that their budget was something like between \$100,000 and \$200,000 a year for the entire board of pharmacy in Massachusetts?"); see Deposition of Francis McAteer, p. 233-34 (asking same questions).

⁴² The U.S. Attorney makes the conclusory statement that the Tennessee Clinic Defendants will not be prejudiced if they are not allowed to depose the Board. (Dkt. 1976-A, ¶ 11). Respectfully, the U.S. Attorney is not in a position to make that judgment. As demonstrated herein, the Board holds information critical to defending the cases. The Tennessee Clinic Defendants will not only be prejudiced, but will be *extremely* prejudiced, if they are required to try these cases without the Board's testimony.

4. The reasons cited in support of the motion for protective Order woefully fail to justify staying discovery of the Board.

In order for the court to impose a stay, the party requesting a stay bears a *heavy burden* to demonstrate a *clear case of hardship*.⁴³

Here, the Board offers a 2½ page memorandum of law devoid of legal precedent⁴⁴ and a cut-and-paste of a previously-filed affidavit. This hardly comes close to carrying the “heavy burden” of establishing a clear case of hardship. The Court need not even consider this Opposition to dismiss the Board’s motion out-of-hand. The Board simply fails to reach the threshold showing necessary to justify the relief sought. Nevertheless, ignoring the absence of evidence to support the motion, the Board’s arguments fail to persuade.

First, the Board’s submission does not cite a *probable* impact a deposition *will have* on the federal criminal prosecution. The Board uses the terms “could” or “might” *seven (7) times* when describing what must be a *real*, as compared to conjectural, hardship. A *possible* impact on a related case is not enough to justify the extraordinary relief the Board requests, particularly when weighed against the extreme prejudice to the Tennessee Clinic Defendants if they are not allowed to depose the Board.

Second, nothing in the Board’s submission suggests that *the Board* has any concerns or objections about presenting a witness.⁴⁵ The motion and memorandum cite *an unrelated federal agency’s* concerns. The Court should not limit the Tennessee

⁴³ *Microfinancial, Inc. v. Premier Holidays Int’l, Inc.*, 385 F.3d 72, 77-78 (1st Cir. 2004).

⁴⁴ LR 7.1(b)(1) requires a memorandum of reasons, “including citation of supporting authorities,” validating the presumption that relief requested will generally be supported by *some* legal precedent.

⁴⁵ This is consistent with the fact that the Board did not mention this burden at any point during the meet-and-confer process.

Clinic Defendants' ability to obtain crucial testimony because a non-Board employee told the Board that something *might* happen if Board witnesses testify.

Third, the Board points to possible interference with the "pending" criminal trial.⁴⁶ This is a blatant misstatement. There is no "pending" criminal trial. Notably absent from the affidavit is any reference to a trial date or even a time period when the trial will occur. The case has not been set for trial.

Fourth, the submitted affidavit speaks of the *possible* involvement of *federal* prosecutors in the preparation of *Massachusetts Board* witnesses. The fact that federal prosecutors will help prepare the Board's witnesses offers no logical support for a protective order in favor of the Board. The Board is not involved in the prosecution of the NECC insiders.⁴⁷ The Board cannot claim that *it* is burdened because the *U.S. Attorney* perceives a need to participate in preparation of witnesses.

The U.S. Attorney's affidavit states that this office of the Justice Department would be burdened by having to meet with these witnesses "so that the team is aware of and understands the details of the witness(es)' testimony and how the testimony would relate to presentation of the government's case[.]"⁴⁸ ⁴⁹ These Defendants expect that the prosecutors met with these witnesses long ago, and will *benefit* from doing so again, regardless of whether the witnesses are testifying in the civil case. To argue that

⁴⁶ Dkt. 1976, p. 2.

⁴⁷ Dkt. 1976-A, ¶ 5.

⁴⁸ Dkt. 1976-A, ¶ 13.

⁴⁹ Notably, there is no affidavit testimony citing the time this is expected to take. Even assuming two witnesses and a hefty 20 hours apiece to prepare them, that is 40 hours of work in a criminal prosecution that, by the U.S. Attorney's own testimony, involves eight governmental agencies and is one of the most significant prosecutions in the country. Surely, in a prosecution this size, the U.S. Attorney's office can lend one of the 120 AUSA's to participate while the Board's attorneys prepare the Board's witnesses.

meeting with these witnesses – meetings the prosecutors must have anyway – is some unbearable burden that justifies a stay of discovery is neither credible nor logical.⁵⁰

Fifth, the argument that governmental agencies are genuinely concerned that a deposition will impact the ability of the NECC insiders to have a fair trial is hollow. The U.S. Attorney claims a fear of “pretrial publicity” that “could affect the rights of the 14 criminal defendants to a fair trial.”⁵¹ Past actions belie this statement. On December 17, 2014, the U.S. Department of Justice issued a 22-paragraph press release quoting nine (9) government officials, *all publicly declaring the guilt of the NECC insiders and describing their reprehensible, criminal acts.*⁵² To, on one hand, voluntarily inject the jury pool with self-congratulatory statements about the NECC insiders’ guilt (statements that no one would read and not automatically deem the insiders guilty⁵³), while, now, on the other hand, *claiming that a deposition of the Board in the civil cases* unacceptably impairs the right to a fair trial, is nonsense.

Sixth, the notion that the Tennessee Criminal Defendants can simply use the Board’s testimony from the criminal case in the civil cases and thus do not need to take the Board’s deposition ignores elementary issues. The testimony is not automatically admissible. Even if it were, the criminal prosecutors will not ask the Board the questions

⁵⁰ Also, the affidavit does not identify the board witnesses the prosecutors intend to call at the criminal trial or even say that the persons who would testify in the civil cases are the same persons who would testify in the criminal case.

⁵¹ Dkt. 1976-A, ¶ 14.

⁵² Press release available at <http://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis> (last accessed June 29, 2015).

⁵³ For instance: “‘As alleged in the indictment, these employees knew they were producing their medication in an unsafe manner and in insanitary conditions, and authorized it to be shipped out anyway, with fatal results,’ said Attorney General Eric Holder. ‘With the indictment and these arrests, the Department of Justice is taking decisive action to hold these individuals accountable for their alleged participation in grievous wrongdoing. Actions like the ones alleged in this case display not only a reckless disregard for health and safety regulations, but also an extreme and appalling indifference to human life.’”

that the Tennessee Clinic Defendants need to defend the claims against them.⁵⁴ Testimony in the criminal cases may be informative, but it is surely no substitute for a designee deposition in the civil cases.

Seventh, the U.S. Attorney states in conclusory fashion – without support – that “[t]he deposition(s) would also prematurely and broadly disclose essential elements of the government’s case-in-chief, allowing the criminal defendants to tailor defenses to fit the anticipated proof.”⁵⁵ The United States Attorney is incorrect. Having paid a portion of their liquid assets in settlement, releasing claims against them and all of their related entities, the NECC insiders will soon be dismissed as defendants in the civil cases. They will not attend the Board’s deposition in the civil cases.⁵⁶ The protective order places the deposition testimony out of reach for the criminal defendants.

Finally, the U.S. Attorney states – again in conclusory fashion – that a deposition of the Board would require the government to prematurely formulate its trial strategy.⁵⁷ The U.S. Attorney offers no explanation, at all, for this surprising statement. It is odd, at best, to imagine that the government’s strategy in this prosecution hinges on *the Massachusetts Board of Pharmacy witnesses’ testimony* issues relevant to Tennessee defendants.⁵⁸ It is hard to understand how a Board deposition on Tennessee issues

⁵⁴ For example, will the prosecutors ask the Board what information potential customers of NECC would have gotten had they requested information about NECC from the Board prior to 2011? Will the federal prosecutors ask the Board questions to establish the Board’s failure to comply with its regulatory duty? Will the federal prosecutors ask the Board about its conclusion in May 2011 that NECC was safe to operate in the state? Of course not. But, this information is vital to the civil cases.

⁵⁵ Dkt. 1976-A, ¶ 14.

⁵⁶ See Common Issue Discovery Deposition Protocol, Dkt. 1426, p. 4.

⁵⁷ Dkt. 1976-A, ¶ 13.

⁵⁸ This very concern has been rejected by this court recently. See *S.E.C. v. O’Neill*, No. 14-CV-13381-ADB, 2015 WL 1505696, at *2-3 (D. Mass. April 1, 2015) (rejecting application for stay of civil proceedings with parallel criminal proceedings: “[t]he government is essentially saying that allowing civil discovery to go forward could give a criminal defendant information earlier than the government would otherwise be required to disclose, and that this premature disclosure could, in effect, cost the government a tactical advantage to which it believes it is entitled....**[T]here is no cognizable harm to the**

would force the government to formulate a trial strategy against NECC's insiders.⁵⁹ This conclusory statement, made without explanation, makes little sense.

* * * * *

The reasons offered by the Board to support the pending motion are ephemeral, at best. They fall well short of the "heavy burden" required to justify a stay, particularly where the stay would strip the Tennessee Clinic Defendants of the ability to obtain evidence they must have to defend the claims against them.

5. The *Microfinancial* factors also weigh against a stay of discovery of the Board

Application of the *Microfinancial* factors leads to the same conclusion, that the Board's motion should be denied.⁶⁰

1. The interests of the civil plaintiff in proceeding expeditiously with the civil litigation

The civil Plaintiffs and Tennessee Clinic Defendants share an interest, in moving the civil cases to trial. The civil Plaintiffs aggressively push for trial dates as soon as possible. They do not want these cases stayed awaiting the criminal prosecution.⁶¹

government in providing such discovery beyond its desire to maintain a tactical advantage....The Court would be more inclined to issue a stay if the pendency of the two investigations threatened to compromise the integrity of the government's investigation, or if having to defend both matters compromised a defendant's ability to defend himself in either proceeding. **In the instant case, however, the government's investigation is complete and charges have been brought. Civil discovery might reveal aspects of the government's criminal case or result in inconsistent statements if witnesses are questioned more than once, but exposing the government's case or testing witness recollections will not fundamentally compromise an ongoing investigation or prosecution.**") (emphasis added).

⁵⁹ We should also presume that, by now, the basic trial strategy in such an important prosecution has been formulated.

⁶⁰ *Microfinancial*, 385 F.3d at 77 (identifying factors to consider when deciding on a stay as (1) the interests of the civil plaintiff in proceeding expeditiously with the civil litigation; (2) the hardship to the criminal defendant, including the burden on him if the criminal and civil case go forward concurrently; (3) the convenience of both the civil and criminal courts; (4) the interest of third parties; (5) the public interest; (6) the good faith of the litigants; and (7) the status of the cases).

⁶¹ The Plaintiffs would, of course, prefer that the Tennessee Clinic Defendants not be permitted to depose the Board at all.

2. The hardship to the criminal defendant

The criminal defendants have not argued that allowing a deposition of the Board would impact their position in the criminal cases at all.

3. The convenience of the civil and criminal courts

Staying a single deposition in the civil cases will not change the courts' burden in managing both the civil and criminal cases.

4. The interest of third parties

The third parties to the criminal case – the Plaintiffs and the Tennessee Clinic Defendants – do not want the criminal case to put the prosecution of the civil cases on hold. Staying the deposition of the Board would seriously prejudice the Tennessee Clinic Defendants.

5. The public interest

The public has an interest in resolution of the criminal case and the civil cases.⁶²

6. The good faith of the litigants

Neither party to this motion takes a position in bad faith.

7. The status of the cases

The civil cases are moving toward a trial date. The criminal case has no trial date and no *projected* trial date. It is entirely possible that the first civil trial could occur before the criminal trial.

* * * * *

If the Court had any doubt as to whether the Board failed to meet its “heavy burden,” application of the *Microfinancial* factors should alleviate that doubt. None weigh in favor of granting the stay requested.

⁶² “The public has an interest in both the prompt resolution of civil cases as well as the fair prosecution of criminal cases.” *Digital Equip. Corp. v. Currie Enters.*, 142 F.R.D. 8, 14 (D. Mass. 1991).

6. Conclusion

For the foregoing reasons, the Tennessee Clinic Defendants respectfully request an order:

1. Denying the Board's motion for protective order,
2. Requiring the Board to produce the documents sought by the subpoena as soon as practicable, and
3. Requiring the Board to present a designee for deposition.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 30th day of June, 2015.

/s/ Chris J. Tardio

Chris J. Tardio